NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS CORPORATION; NOVARTIS PHARMACEUTICALS CORPORATION; and NOVARTIS INTERNATIONAL AG, Plaintiffs, v. LUPIN LTD, and LUPIN PHARMACEUTICALS, INC. Defendants.	Civ. No. 06-5954 (HAA) (ES) **OPINION and ORDER**

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ACKERMAN, Senior District Judge:

This patent suit arises from Lupin's marketing of generic versions of Novartis's product Lotrel®, a prescription drug medication for the treatment of hypertension that is covered by Novartis's U.S. Patent No. 6,162,802 ("the '802 patent"). This Court had scheduled a *Markman* hearing in this matter for February 19, 2009. However, a week prior to that date, the parties stipulated and agreed to a construction of the claim term that was to be the main subject of the Court's hearing. The Court approved the parties' stipulation on February 13, 2009. Remaining now before the Court are the parties' requests to reconsider the Court's previous claim constructions issued in the Court's opinion in the related matter of *Novartis Corp. v. Teva Pharmaceuticals USA, Inc.*, 565 F. Supp. 595 (D.N.J. 2008). This Court will adhere to the claim constructions previously determined in *Novartis v. Teva*, and will apply them in this matter.

I. INTRODUCTION

A. Factual Background and Procedural History

The '802 patent, entitled "Synergistic Combination Therapy Using Benazepril and

Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor," was filed on March 10, 1992. On December 19, 2000, after more than eight years of prosecution, the United States Patent and Trademark Office ("PTO") issued the '802 patent to Ciba-Geigy Corp., a predecessor of Novartis, as assignee of inventors Joseph Papa and Marc M.J. Henis. Generally, the '802 patent claims methods for the treatment of cardiovascular disorders, including hypertension, and pharmaceutical compositions combining two different anti-hypertensive agents, amlodipine and benazepril.

On March 3, 1995, Novartis received approval from the FDA to market Lotrel in six dosage strengths: 2.5/10 mg (amlodipine besylate/benazepril hydrochloride), 5/10 mg, 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg. Lotrel is approved for the treatment of hypertension and has been marketed in the United States since its approval. In accordance with 21 U.S.C. § 355(b)(1), Novartis filed with the FDA the patent numbers and expiration dates for each patent covering Lotrel. The FDA publishes this information in a list of innovator drug products and their related patent information called Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." 21 U.S.C. § 355(j)(7)(A). The Orange Book listed four patents for Lotrel; however, the '802 patent represents the only remaining unexpired patent, and the only patent-at-issue in this matter.

In 2006, Lupin filed an Abbreviated New Drug Application ("ANDA"), No. 78-466, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), to market generic counterparts to Lotrel® capsules. Lupin sent a statutorily-required notice letter to Novartis, asserting that its generic combination capsules do not infringe the '802 patent and that the '802 patent is invalid. *See* 21 U.S.C. § 355(j)(5)(B)(i); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d

1323, 1327 (Fed. Cir. 2001). Novartis filed suit against Lupin in December 2006, triggering an automatic stay of FDA approval for Lupin's ANDA, and thus precluding the marketing of Lupin's generic combination capsules for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). Discovery is now complete.

Before the Court addresses the relevant claims and the parties' arguments, this Court will briefly summarize the issues that were before the Court in *Novartis v. Teva*, because the Court's constructions in that suit are again disputed in the present matter. On July 16, 2008, this Court issued an opinion on three claim construction issues. *See Teva*, 565 F. Supp. 2d 595. First, the Court defined the claim language "physically separated" in the following manner: The two ingredients, benazepril and amlodipine, are not in physical contact with each other. This construction maintains the structural element that "physically separated" implies. Second, this Court construed Claim 1, as such: "Daily dose" covers more than just "single dosage forms." To the extent that the two agents are given in "a single dosage form," the "physically separated" limitation of Claim 19 applies to Claim 1. Third, and important to the present matter, this Court defined "a daily dose" as the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day.

In this case, after the parties' stipulation, there are three remaining claim construction disputes before this Court, all of which the Court has previously addressed in some manner. The first two involve, again: the meaning of "physically separated" and whether that term applies to Claim 1 insofar as Claim 1 or dependent claims involve a single dosage form. The third issue has also already been addressed in *Teva*: whether "a daily dose" refers to a once-daily dosing of benazepril and amlodipine. However, Lupin presents additional arguments and evidence not

previously before the Court that it contends merits reconsideration: whether "a daily dose" refers to a once-daily dosing of benazepril and amlodipine.

II. DISCUSSION

A. The *Markman* Hearing

There are two steps in a patent infringement analysis. First, the court must determine the proper construction, or meaning, of the disputed claim or claims. Second, findings must be made as to whether the accused product or method infringes the asserted claim as properly construed. *See Markman v. Westview Instruments*, 517 U.S. 370, 377-90 (1996). Under *Markman*, claim construction is a matter of law to be decided only by the court, whereas infringement is a question left to the factfinder. *Id.*

A *Markman* hearing may be held before, during, or after discovery, and even, in theory, during the infringement trial or on post-trial motions. *See Elf Atochem N. Am., Inc. v. Libbey-Owens-Ford Co.*, 894 F. Supp. 844, 850 (D. Del. 1995). Here, of course, the District Court did not hold a new *Markman* hearing because, following the parties' stipulation, the only remaining issues before the Court concern constructions already decided by this Court.

A fundamental principle of claim construction is that patent claims must have the same meaning to all persons at all times, and that the meanings of the claims are determined and fixed at the time the PTO issued the patent. *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338 (Fed. Cir. 2005) (en banc) ("Claim interpretation requires the court to ascertain the meaning of the claim to one of ordinary

skill in the art at the time of invention."). The need for uniformity of claim construction and concerns about fairness to competitors inform the policy of reserving the claim construction function to the trial judge. *See Markman*, 52 F.3d at 987 ("The more appropriate analogy for interpreting patent claims is the statutory interpretation analogy. Statutory interpretation is a matter of law strictly for the court. There can be only one correct interpretation of a statute that applies to all persons.").

In some instances, claim construction may be dispositive of the entire case because the likelihood of success for one side is greater on the issue of infringement based on the court's construction. *See*, e.g., *Nystrom v. Trex Co.*, 424 F.3d 1136, 1140-41 (Fed. Cir. 2005) ("Based on the district court's claim construction ruling, Nystrom conceded that he could not prove his infringement case against TREX."). In such cases, the court's and the litigants' resources may be saved by consenting to judgment. Even if the claim construction is not dispositive of the case, it will lay the groundwork for the ensuing infringement trial.

B. General Principles of Claim Construction

In interpreting a disputed claim, the court looks primarily to the intrinsic evidence in the record, "*i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing *Markman*, 52 F.3d at 979). Intrinsic evidence is the "most significant source of the legally operative meaning of disputed claim language." *Id.* First, the court must look to the words of the claim itself to define the proper scope of the

claimed invention. When interpreting the words of the claim, "a court must presume that the terms in the claim mean what they say," *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999), and the court must give those words their ordinary and customary meaning, as viewed by a person of ordinary skill in the art in question at the time of the invention, *Phillips*, 415 F.3d at 1312-13 ("It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed.").

Although an invention is defined by a patent's claims, they "do not stand alone." *Phillips*, 415 F.3d at 1315. Instead, claims "are part of 'a fully integrated written instrument,'" *id*. (citing *Markman*, 52 F.3d at 978), consisting principally of a written description of the invention, 35 U.S.C. § 112 para. 1, often referred to as the specification,[1] and concluding with the claims, *id*. para. 2. "For that reason, claims 'must be read in view of the specification, of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979).

The third step in claim construction, and most important to the present matter, entails consideration of a patent's prosecution history. The prosecution history of a patent, also known as the "file wrapper," "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope

[1] As defined by 35 U.S.C. § 112, the specification of a patent is technically the written description of the disclosed invention plus the claims. 35 U.S.C. § 112 para. 2. However, as used widely by courts and practitioners, the term "specification" herein refers only to the written description of the invention, excluding the claims.

narrower than it would otherwise be."[2] *Phillips*, 415 F.3d at 1317. When construing claims, one of the purposes of consulting the prosecution history is to "exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1580 (Fed. Cir. 1988) (citation omitted). Importantly, "where the patentee has *unequivocally disavowed* a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g., Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (emphasis added); *see also id.* ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution.").

For example, during the application process, a patent examiner may require the applicant to limit the scope of his or her proposed claims so as not to include prior art within their ambit. An applicant may also limit the scope of his or her proposed claims in the process of distinguishing his or her invention over the prior art in order to obtain a patent. When an applicant explicitly surrenders or disclaims subject matter in this manner, the disclaimer becomes part of the prosecution history. If the application ultimately issues as a patent, the patent holder is bound by his or her prior disclaimers. *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed. Cir. 1998) ("[E]xplicit

[2] A patent's prosecution history "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. This record also includes "any express representations made by the applicant regarding the scope of the claims." *Vitronics*, 90 F.3d at 1582.

statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim."). Thus, examination of a patent's prosecution history and the application of prosecution disclaimer is a helpful tool during claim construction as it "ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers." *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005).

The Federal Circuit, however, has warned that a court's reliance on prosecution history must be tempered with the recognition that a "prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." *Phillips*, 415 F.3d at 1317. As such, it is important to acknowledge that a prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* Accordingly, prosecution disclaimer is not appropriate in instances "where the alleged disavowal of claim scope is ambiguous," or where remarks made by an inventor to overcome a rejection may be viewed "as amenable to multiple reasonable interpretations." *Omega*, 334 F.3d at 1324 (citing *N. Telecom Ltd. v. Samsung Elec. Co.*, 215 F.3d 1281, 1293-95 (Fed. Cir. 2000)). Thus, "for prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Id.* at 1325-26; *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) (reiterating that "arguments made to distinguish prior art references" will be considered disavowals "only if they constitute clear and unmistakable surrenders of subject matter").

Lastly, although "[i]n most situations, an analysis of the intrinsic evidence alone

will resolve any ambiguity in a disputed claim term," a court may rely on extrinsic evidence, such as expert and inventor testimony, dictionaries, and learned treatises, if an analysis of the intrinsic evidence does not give clarity to a disputed claim term. *Vitronics*, 90 F.3d at 1583. The sequence in which the various sources are consulted is not important; rather, appropriate weight must be given to those sources "in light of the statutes and policies that inform patent law." *Phillips*, 415 F.3d at 1324. Nevertheless, a court should not rely on extrinsic evidence when the public record unambiguously defines the scope of the claimed invention. "The claims, specification, and file history, rather than extrinsic evidence, constitute the public record . . . on which the public is entitled to rely." *Vitronics*, 90 F.3d at 1583. Notwithstanding the disfavored treatment of extrinsic evidence, *Vitronics* instructs that judges may consult technical treatises and dictionaries to gain a better understanding of the underlying technology. *Id*. at 1584 n.6. Judges may even adopt the dictionary definition of terms as long as the definition does not contradict the intrinsic evidence associated with related patent documents. *Id*.

As discussed above, Lupin reargues the issues regarding "physically separated" and whether that limitation applies to Claim 1 insofar as Claim 1 involves a single dosage form. Lupin largely restates arguments made by Teva, and the Court reaffirms and adopts those relevant constructions made in *Teva*, 565 F. Supp. 2d at 614, 616. The only issue requiring further comments is a re-assessment of the interpretation of "a daily dose."

C. The Court maintains its earlier interpretation that the limitation "a daily dose" means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of

administrations in that single day.

This Court now addresses, for purposes of claim construction, the meaning of "a daily dose" as that limitation applies in Claims 1 and 19. Claim 1 covers "a method of treating . . . hypertension . . . , consisting of administering *a daily dose* of (a) benazepril . . . and (b) amlodipine." ('802 patent, col. 5, ll. 6-21 (emphasis added).) Similarly, Claim 19 covers "[a] pharmaceutical composition consisting essentially of *a daily dose* of (a) benazepril . . . and (b) amlodipine." (*Id.*, col. 6, ll. 8-19 (emphasis added).) The essential dispute over the term "a daily dose" is whether that term means the total amount of amlodipine and benazepril given in a 24-hour period, or the number of times amlodipine and benazepril are each given in a 24-hour period. In *Teva*, this Court concluded that "'a daily dose' means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day." 565 F. Supp. 2d at 619.

Lupin argues that Novartis limited the scope of the '802 patent to once-per-day administration during prosecution of the patent. Specifically, Lupin contends that evidence in the prosecution history not before the Court in *Teva* provides clear evidence that "a daily dose" means "once-daily." In other words, Lupin argues that Novartis unequivocally disavowed that "a daily dose" means anything other than "once-daily."

Lupin's argument concerning the prosecution history of the '802 patent extends from the Court's discussion of a nearly-identical issue in *Teva*: the Maclean reference. In that case, Teva argued that Novartis received an "obviousness" rejection from the patent

examiner for the '802 patent. The patent examiner stated that the Maclean reference disclosed administering captopril (which is an ACE inhibitor of the same class as benazepril) and amlodipine and, therefore, the '802 patent proposal was "obvious" based upon the Maclean reference. *Teva*, 565 F. Supp. 2d at 618. In responding to the patent examiner's rejection, Novartis attempted to distinguish the '802 patent from the Maclean reference with the following argument:

> In this case, there is neither teaching, suggestion or motivation in Maclean to produce Applicants' method of treating hypertension and other conditions consisting of administering *a daily dose* of benazepril and amlodipine as claimed nor Applicants' pharmaceutical composition comprising benazepril and amlodipine as claimed. Maclean teaches the therapeutic usefulness of a *once-daily* dose of amlodipine (10 mg) given with twice-daily doses (25 mg each) of captopril. This reference does not teach *a once-daily dose* of an ACE inhibitor to treat hypertension.

(Carlan Decl., Ex. 11 (emphases added).) Teva argued before this Court that Novartis could not "stand on the dictionary definition of 'daily dose' because Novartis provided its own definition of the term in its attempt to distinguish the '802 patent from prior art." *Teva*, 565 F. Supp. 2d at 618. Teva insisted, rather, that "Novartis should be bound by the equation of 'once daily' with 'a daily dose,' regardless of the dictionary definition of the latter term." *Id.*

This Court rejected Teva's argument. First, Novartis explained that it "did *not* argue that the '802 patent taught 'once-daily' administration of benazepril, but only that benazepril's chemical structure was sufficiently different from that of captopril such that once-daily administration was possible and, therefore, the invention embodied in the '802 patent was not obvious." *Id.* (quoting Novartis Br. at 23.) Ultimately, Novartis successfully argued to the patent

examiner that, in the Court's words, "its invention was not an obvious extension of Maclean because the '802 patent has *possible* applications that were *impossible* in Maclean." *Id.* at 618. Second, this Court examined *Purdue Pharma v. Endo Pharmaceuticals*, 438 F.3d 1123, 1136 (Fed. Cir. 2006), where the Federal Circuit found no "clear disavowal" based on facts similar to those in *Teva*. Thus, this Court concluded that "[w]hile Teva has raised a reasonable argument that the prosecution history amounts to a disavowal, . . . Teva has not demonstrated . . . that disavowal to a clear and unmistakable degree." *Teva*, 565 F. Supp. 2d at 619.

Here, Lupin attempts a double dose of the Maclean reference, but still will not enjoy the desired cure. Citing the same Maclean reference, Lupin quotes the next portion of Novartis's statement before the patent examiner to distinguish the '802 patent from the Maclean reference:

> Thus, since Maclean does not disclose *a once-daily dosage of captopril or other ACE inhibitor in combination with amlodipine*, Applicants respectfully submit that this reference does not teach, suggest or motivate one to produce Applicants' claimed invention. In fact, *Maclean teaches away* from an antihypertensive therapy consisting of a *single daily dose of ACE inhibitor in combination with amlodipine* and as such does not render Applicants' invention obvious.

(Amundson Decl. Ex. 33 (emphases added).) Lupin argues that this later passage demonstrates that Novartis unequivocally disavowed its interpretation of "a daily dose" to include anything but a once-daily dosage. Yet, this second statement by Novartis is difficult to distinguish from its first. In both, Novartis seems to offer that the Maclean reference is distinguishable from the '802 patent because the prior art did not cover a single-daily dosage. Further, this Court has already reviewed this second statement in Teva's papers (*see* Teva Br. at 38), and cited to it in finding no unequivocal disavowal, *see Teva*, 565 F. Supp. 2d at 618. Thus, this second statement does not

truly present a new issue for the Court.

Lupin cites a compelling case from the Federal Circuit, *Elkay Manufacturing Co. v. Ebco Manufacturing Co.*, 192 F.3d 973, 978 (Fed. Cir. 1999), but the Court believes the more recent decision of *Purdue Pharma*, referenced by this Court in *Teva*, is more resonant. In *Purdue Pharma*, the Federal Circuit reversed the district court's finding of unequivocal disavowal. 438 F.3d at 1136. There, the plaintiff sought to patent a controlled release oxycodone formulation intended to control pain in humans. A surprising byproduct of this formulation was that the invention controlled pain over a "four-fold dosage range." *Id.* at 1135. During the prosecution of its patent, the plaintiff distinguished its formulation from similar prior art that employed an "eight-fold range." *Id.* at 1127 (internal quotation omitted). Rejecting the district court's finding of disavowal, the Federal Circuit found: "Rather than presenting the four-fold dosage range as a *necessary feature* of the claimed oxycodone formulation, [the plaintiff] described it as a property of, or a result of administering" its formulation. *Id.* (emphasis added). As plaintiff even stated during the prosecution, "by choosing th[ese] parameters in the controlled-released formulation, it is *possible* to acceptably control pain over a substantially narrower dosage range [*i.e.*, four-fold] than through the use of other" formulations. *Id.* (emphasis added). Thus, the court held that the plaintiff's prosecution history did not satisfy the defendant's heavy burden to show clear disavowal. *Id.*

This Court found *Purdue Pharma* convincing in *Teva*, and the Court remains persuaded here. In this case, the prosecution history shows that Novartis differentiated the '802 patent from the Maclean reference because the Maclean reference "teaches away" from "a single daily dose." In neither statement concerning the Maclean reference, though, does Novartis clearly describe a

single daily dose as a necessary feature of the entire '802 patent. As it argued in *Teva*, Novartis contends that its "exchange with the patent examiner was not a disclaimer of the ordinary meaning of 'daily dose,' but mere advocacy as to why Maclean's disclosure of captopril in the combination does not render obvious the use of benazepril in the claimed invention." (Novartis Reply Br. at 3.) Similar to the plaintiff's statement in *Purdue Pharma* that its patent was distinguishable from prior art because the four-fold dosage range was "possible," here, "Novartis successfully demonstrated that its invention was not an obvious extension of Maclean because the '802 patent has *possible* applications that were *impossible* in Maclean." *Teva*, 565 F. Supp. 2d at 618-19.

Lupin makes a reasonable argument that Novartis disclaimed a broad interpretation of "a daily dose," but Novartis's statements are "amenable to multiple reasonable interpretations." *Omega*, 334 F.3d at 1324; *see also Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375 (Fed. Cir. 2008) ("Prosecution disclaimer does not apply to an ambiguous disavowal."). It is reasonable to read Novartis's statements during prosecution as permitting, but not mandating, a single daily dose under the '802 patent. Thus, Lupin has not met its heavy burden to show an unequivocal disavowal, and the Court rejects its construction of "a daily dose" to the extent that it relies upon a purported disavowal in the prosecution history. *See Lucent Tech., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1211 (Fed. Cir. 2008) (refuting clear disavowal where the "prosecution clearly distinguish[ed] the claim[ ]" from prior art, but nevertheless did "not constrain" the claim on that distinction); *Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Com'n*, 383 F.3d 1352, 1375 (Fed. Cir. 2004) (rejecting theory of claim disavowal or disclaimer where "[patentee] stated only that the . . . reference was incapable of performing a certain type of

search, not that the scope of the claimed invention was limited to that particular type of search."). Instead, this Court maintains its construction of the term in accordance with the dictionary definition and its decision in *Teva*: "A daily dose" means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day.

III. CONCLUSION & ORDER

For the foregoing reasons, this Court adheres to its earlier constructions of the '802 patent set forth in the related matter of *Teva*, 565 F. Supp. 2d at 595, and adopts them in this matter.

SO ORDERED.

Newark, New Jersey
Dated: March 17, 2009

/s/ Harold A. Ackerman
U.S.D.J.